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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/694,136

10/27/2003

Gerhard Bienhaus

18583-US1

3248

22829

7590

11/28/2008

Roche Molecular Systems, Inc.

Patent Law Department

4300 Hacienda Drive

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EXAMINER

RAMILLANO, LORE JANET

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

11/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/694,136	Applicant(s) BIENHAUS ET AL.	
	Examiner LORE RAMILLANO	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/12/08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2 is/are allowed.
- 6) ☒ Claim(s) 1 and 4-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Applicant's reply filed on 9/12/08 is acknowledged. Claims 1, 2, and 4-7 are pending and are under examination.

Prior art rejections

2. The rejection by Fujishiro is maintained. The rejection over Bienhaus in view of Fujishiro is withdrawn.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 1 and 4-7** are rejected under 35 U.S.C. 102(b) as being anticipated by Fujishiro et al. ("Fujishiro," US 5645723).

Fujishiro teaches a process for isolating a purified biological material comprising the following steps: a) placing biological materials in separate lysis vessels of a lysis unit comprising two or several lysis vessels in a predetermined geometric arrangement, b) adding lysis liquids to the biological materials in the lysis vessels, c) transferring the liquids in the lysis vessels into a matrix unit containing matrix vessels with outlet openings whose number corresponds to the number of lysis vessels and a matrix is located in each of the matrix vessels to which the biological material to be purified binds, d) extracting the liquids in the matrix vessels through the outlet openings during which the liquids flow through the matrices, e) placing the matrix unit on a collecting unit with collecting vessels which are arranged such that at least the outlet openings of the matrix vessels extend into the collecting vessels, f) filling the matrix vessels with elution

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fluid, g) extracting the elution fluids from the matrix vessels through their outlet openings during which the elution fluids flow through the matrices and the elution fluids which are enriched with biological material are collected in the collecting vessels; and (h) closing the collecting unit with a closure unit. (i.e. figs. 2-8, column 2, line 58 to column 8, line 48).

Fujishiro further teaches that the biological materials are added to the lysis vessels by only opening the lysis vessel into which material is to be added and the caps of the other lysis vessels of the lysis unit are closed and the caps of the matrix unit are in the leaned-to position before addition of the lysis liquids (i.e. p. fig. 7, col. 4, lines 20-46).

Fujishiro further teaches a process as comprising the steps: a) storing data which identify a biological sample, b) allocating the data relating to the biological sample to data which identify the lysis unit as well as the position of the lysis vessel within the lysis unit into which the sample is added, c) allocating data which identify the matrix unit into which the lysis liquids are added to data which identify the lysis unit, d) allocating data which identify the collecting unit in which the elution liquid from the matrix unit is collected; and the liquids are transferred from the lysis unit into the matrix unit by removing liquid from a lysis vessel and adding it to the matrix vessel of the matrix unit that is in a corresponding position. (i.e. figs. 2-8, column 2, line 58 to column 8, line 48).

Response to Arguments

4. Applicant's arguments, see p. 2-3, filed 9/12/08, with respect to the rejection over Bienhaus in view of Fujishiro have been fully considered and are persuasive. This rejection has been withdrawn.

5. Applicant's arguments filed 9/12/08, with regard to the rejection by Fujishiro, have been fully considered but they are not persuasive.

In response to applicant's argument that Fujishiro lacks the step of "closing the collecting unit with a closure unit," as recited in claim 1, examiner respectfully disagrees. As shown in figs. 1 and 2 of Fujishiro, it appears that the main body (1) is the recited, "closure unit." The main body is a closure unit for the components inside the main body, which include the collecting unit.

Furthermore, applicant should note that the use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. Patents are part of the literature of the art, relevant for all they contain, which include the disclosure indicated in the "Prior Art" section of the patent.

Allowable Subject Matter

6. Claim 2 is allowed.

7. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record (Fujishiro) fails to teach or fairly suggest the step whereby the liquids in the matrix vessels are extracted by centrifugation, in combination with the remaining features and elements of the claimed invention.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LORE RAMILLANO whose telephone number is (571)272-7420. The examiner can normally be reached on Mon. to Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797

Lore Ramillano
Examiner
Art Unit 1797